Applicants: Marc F. Char U.S.S.N.: 09/012,846

REMARKS

Claims 28-45 are pending, claims 2, 5-11, and 23-27 having been canceled by the present amendment. New claims 28 and 38 are supported by originally-filed claim 4; disclosure on page 5, lines 6-9, and disclosure on page 45, line 11, to page 61, line7, of the specification. New claim 38 is further supported by disclosure on page 10, lines 18-24, of the specification. New dependent claims 29-32 and 39-42 are supported by disclosure on page 29, lines 8-10, of the specification. New dependent claims 34-36 and 43-45 are supported by disclosure on page 12, lines 4-5 of the specification and on page 15-16 of the disclosure. No new matter has been added by this amendment.

Claims 2, 5-11, and 23-27 were rejected for overbreadth, lack of enablement, and for anticipation. Applicant has now canceled claims 2, 5-11, and 23-27 and added new claims 28-45. The new claims are drawn to treating damaged hippocampal tissue and to restoring a function of damaged hippocampal tissue by by contacting the tissue with certain morphogens.

The Examiner's rejections in Paper No. 11 are addressed below in view of the new claims.

35 U.S.C. §102

Claims 2, 5-11, and 27 were rejected for anticipation by Wang et al. On page 8, lines 1-7, of Paper No. 11, the Examiner states:

Applicants claims do not teach sufficient structural or functional limitations such that Wang's morphogens or methods are excluded from the scope of the claimed invention. Instant claims are drawn to neural disorders including cognitive dysfunction, reducing memory dysfunction, trauma, oxygen deprivation, glucose deprivation, neurotoxin, and neurodegenerative disorders, dementia, and to the disorders as claimed in claims 5-11 and 27. These defects and disorders are all encompassed by Wang's description of neural defects, neural damage or neural conditions, and thus instant claims appear to be anticipated by Wang.

Applicant has now amended the claim to require the step of contacting damaged hippocampal tissue (new claim 28) or a hippocampal cell (new claim 38) with certain

Applicants: Marc F. Cha U.S.S.N.: 09/012,846

morphogens. Wang et al. neither disclose nor suggest specifically contacting hippocampal cells or tissue. Therefore, the new claims are not anticipated by Wang et al.

35 U.S.C. §112, first paragraph

Claims 2, 5-11, and 27 were rejected for overbreadth and lack of enablement.

With respect to claim breadth, the Examiner argued that the scope claims 2, 5-11 was not commensurate with the disclosure but acknowledged a working example, which describes dendrite outgrowth and synaptogenesis. On page 5, lines 12-17, of Paper No. 11, the Examiner states:

This example teaches at p. 61, lines 1-7 that addition of morphogen to cultured hippocampal neurons significantly accelerates dendritic outgrowth and development as shown by tapering and branching of these cells at 3 days in vitro (as compared to 14 days in normal controls, increased numbers of synapses and increased MAP2 expression. Yet, this example as previously set forth, does not provide a nexus for the claims as recited. No teachings are commensurate in scope with protecting cognitive dysfunction, or reducing memory dysfunction.

Accordingly, claims 2, 5-11, and 27 were canceled. New claims 28-45 were added. As is discussed above, these claims are drawn to treating damaged hippocampal tissue and to restoring a function of damaged hippocampal tissue by by contacting the tissue with certain morphogens. Applicant submits that the new claims are commensurate with the teachings and the example provided in the specification, and therefore, respectfully request withdrawal of this rejection.

With respect to enablement/claim breadth, the Examiner states:

no sequence information is recited in the claim and that thus contrary to applicants assertion insufficient structural and functional limitations exist such that the skilled artisan can either make, use or even identify the invention claimed. A recitation of a protein by name alone provides no structural or functional limitations. (see page 4, lines 12-16 of Paper No. 11)

First, the new claims added by this amendment functionally limit the morphogens encompassed by the claims. For example, only morphogens, which induce dendritic

Applicants: Marc F. Char U.S.S.N.: 09/012,846

outgrowth of a hippocampal neuron, are encompassed by new claims 28-36. Similarly, new 38 specifically requires that the morphogen stimulates synapse formation between hippocampal neurons. Methods of determining whether or not a morphogen has these functions is described in detail in the specification, and these limitations omit inoperative embodiments from the scope of the claim.

Second, since new claims 29-32 and 39-42 (which are drawn to OP-1 polypeptides) specifically recite a polypeptide sequence, Applicant believe that this rejection is most in view of those claims.

Third, with respect to claims 28, 34-36, 38, and 43-45 (which recite BMPs-2, 5, and 6 without reference to a specific SEQ ID NO), one skilled in the art would have no difficulty indentifying the invention, i.e., determining which morphogens fall in or outside the scope of the claim. Moreover, such an artisan would also not have to resort to undue experimentation to practice the invention, because, on both points, the recited morphogens were well-known and characterized at the time of the invention. To wit, the specification (at page 17, lines10-20) provides examples of the wealth of information pertaining to the recited morphogens, which was available at the time of the invention. Applicant submits that undue experimentation would not be required to determine the sequence of a BMP-2, BMP-5, or BMP-6 polypeptide at the time of the invention, nor would there be any confusion among those skilled in the art as to what was meant by the recited claim terms.

In view of the foregoing claim amendments and arguments made herein, Applicant submits that the claims are in condition for allowance and request the withdrawal of the rejections under U.S.C. section 112.

- Applicants: Marc F. Cha U.S.S.N.; 09/012,846

CONCLUSION

Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 (Reference No. 00960-510).

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39,529 Ingrid A. Beattie, Reg. No. 42,306

Attorneys for Applicants c/o MINTZ, LEVIN

One-Financial Center

Boston, Massachusetts 02111

Tel: (617) 542-6000 Fax: (617) 542-2241

Date: January 25, 2001

TRADOCS:1428485.1(%M85011.DOC)